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AUG 1 9 2011

#### 510(k) Summary

In accordance with 21 CFR 807.92(c) the following summary of information is provided:

Date Prepared: August 18, 2011

Submitter: Medicis Technologies Corporation

11818 North Creek Parkway North

Bothell, WA 98011

Contact Person: Michael A. Hoffman, MPH

Vice President - Regulatory Affairs and Quality Systems

Medicis Technologies Corp.

11818 North Creek Parkway North

Bothell, WA 98011

Telephone: 425.420.2135

Facsimile: 425.420.2335

FR Number: 21 CFR 878.4590

Product Code: OHV

Classification Focused Ultrasound for Aesthetic Use

Name

Common Name: Focused Ultrasound Stimulator for Aesthetic Use

Trade Name: LipoSonix® system Model 1

Regulatory Class: Class II

Classification Division of General, Restorative and Neurological Devices;

Advisory General Surgery Devices Branch

Committee:

Special Controls: Class II Special Controls Guidance Document: Focused

Ultrasound Stimulator System for Aesthetic Use (July 20,

2011)

Predicate K072505 Ulthera System, Model 8850-0001

Device(s):

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**Indications for** The *LipoSonix* system delivers high intensity focused Use: ultrasound (HIFU) energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect.

> The LipoSonix system is specifically indicated for noninvasive waist circumference reduction.

Contraindications: A patient is ineligible for treatment with the LipoSonix system if any of the following criteria are met:

- The patient is a female who is pregnant, may be pregnant, or is lactating. Female patients of child bearing age should have a negative pregnancy test before being treated with the *LipoSonix* system.
- The patient has less than 1.0 cm of adipose tissue thickness beyond the selected focal depth in the area to be treated.
- Hernia in the area to be treated.

Device Description: The LipoSonix system is a cart-based system intended for non-invasive waist circumference reduction. The *LipoSonix* system uses ultrasound energy to disrupt subcutaneous adipose tissue (soft tissue). The system consists of a base, a treatment head (which contains the transducer) and a treatment arm in one unit.

Technology:

The LipoSonix system accomplishes its intended use through the use of precisely targeted high intensity focused ultrasound energy that produces thermal coagulative necrosis and cellular disruption in the subcutaneous adipose tissue (soft tissue). This thermal energy also causes collagen to contract. Thus creating a dual tissue response. The destroyed adipose tissue is subsequently cleared via an inflammatory response by macrophages that transported the destroyed cells and their contents to the liver via the lymphatic system.

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### Determination of Substantial Equivalence:

**Determination of** Summary of Non-Clinical Tests:

The system has been found to conform to the system essential specifications, thermal, electrical, electromagnetic and mechanical safety, and has been found to conform to FDA consensus, medical device safety standards and international harmonized standards.

The following risks as identified in the FDA special control guidance document entitled, "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use" have been addressed.

- Thermal Injury from Focused Ultrasound Exposure (Thermal Damage)
- Mechanical Injury from Focused Ultrasound Exposure (Cavitation or other Mechanical Damage)
- Ocular Injury
- Electrical Shock
- Inflammation/Foreign Body Response
- Use Error

#### Performance Data:

The *LipoSonix* system was evaluated in a multicenter, randomized study. Treatment with the *LipoSonix* system was shown to be superior to a sham control in reducing waist circumference, meeting the pre-specified primary endpoint of the study. The 59 J/cm² treatment group demonstrated a 1.01 cm greater waist circumference reduction as compared to sham. The least square (LS) mean change from baseline to 12 weeks of the waist circumference in the same 59 J/cm² group was -2.44 cm. On average, the mean change in waist circumference of approximately 2.55 cm (1 inch) compared to baseline that was demonstrated in the 59 J/cm² treatment group. This could equal one dress or pant size.

The safety of treatment with the *LipoSonix* system was assessed through 24 weeks post-treatment. The AEs resulting from treatment with the *LipoSonix* system during this study were mostly mild, short-lived in duration, and resolved without incident. There were no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) related to treatment with the investigational device.

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Substantial Equivalence:

The *LipoSonix* system is substantially equivalent to the Ulthera<sup>™</sup>, Inc., *Ulthera* System, Model 8850-0001 (K072505) device.

The LipoSonix system has the same intended use as the Ulthera system, namely performing a non-invasive treatment to achieve a desired aesthetic effect. The LipoSonix system uses the same technological principles as the Ulthera system, namely HIFU, to thermally coagulate soft tissues which result in the aesthetic affect. The mechanism of action for both devices is essentially the same as well. Coagulated soft tissue is removed by normal healing processes of the body resulting in an aesthetic affect. Both devices can deliver more than one energy dose at several different depths within the body.

Therefore, the *LipoSonix* system is substantially equivalent to the predicate device.







Food and Drug Administration 10903 New Hampshire Avenuc Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

Medicis Technologies Corp. % Hogan Lovells US LLP Mr. Jonathan S. Kahan Columbia Square 555 Thirteenth Street, NW Washington, District of Columbia 20004

AUG 1 9 2011

Re: K100874

Trade/Device Name: LipoSonix® System Model 1

Regulation Number: 21 CFR 878.4590

Regulation Name: Focused ultrasound stimulator system for aesthetic use

Regulatory Class: Class II Product Code: OHV Dated: August 16, 2011 Received: August 16, 2011

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Director

Division of Surgical, Orthopedic and Restorative Devices Office of Device Evaluation Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K100874

### **Indications for Use**

Device Name: LipoSonix <sup>®</sup> system Model 1
Indications For Use:
The <i>LipoSonix</i> system delivers high intensity focused ultrasound (HIFU) energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect.
The <i>LipoSonix</i> system is specifically indicated for non-invasive waist circumference reduction.
Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)  (Division Sign-Off)  Division of Surgical, Orthopedic,  and Restorative Devices  Page 1 of 1
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